Check for updates

Lasers in Surgery and Medicine 50:732–737 (2018)

A Customized Approach for Arm Fat Reduction Using Cryolipolysis

Jason K. Rivers, BSc, MD, FRCPC, FAAD,[1,2*] **Marcie Ulmer,** MD, FRCPC, FAAD,[1,2] **Brianne Vestvik,** BSc, MSc,[1] **and Sherisse Santos,** RN, BScN, MScN: FNP(P)[1]

[1]*Pacific Derm, Vancouver, British Columbia, Canada*

[2]*Department of Dermatology and Skin Science, University of British Columbia, British Columbia, Canada*

Objectives: Cryolipolysis of the arms has been demonstrated to be an effective treatment for non-invasive reduction of subcutaneous fat. This study evaluated the safety and efficacy of the concurrent use of a new commercially-available small applicator in conjunction with an existing medium sized applicator for the customized treatment of arm fat.

Methods: Bilateral arms of 15 eligible subjects were simultaneously treated using one or two vacuum applicators with flat contours. Either a medium or small cryolipolysis applicator with an oblong cup-shaped cooling surface was selected to treat upper arm fat. The shape of the fat bulge in each subject's arm was assessed and up to two treatment cycles (−11°C for 35 minutes each) were delivered to each arm in one session, based upon investigator discretion. Throughout the procedure and at the completion of each treatment cycle, investigators assessed the subject's level of comfort, as well as sensory and motor nerve effects. Post-treatment manual massage was performed, and clinical assessments of each treatment site were recorded. Adverse events were recorded to monitor procedural safety. Baseline and 12 weeks post-treatment photographs and ultrasound measurements were taken to assess efficacy. Subject questionnaires were administered to evaluate satisfaction.

Results: Fifteen female subjects (mean age of 51.1, mean BMI of 26.8) completed the study. Ultrasound imaging revealed statistically significant fat layer reduction of 2.5 mm (SD ± 2.4 mm, 95%CI 1.6–3.3). Subject surveys administered 12 weeks post-treatment demonstrated 87% satisfaction with the arm cryolipolysis procedure. A panel of blinded, independent physicians correctly identified 83% of the before and after photos. Clinical assessments found adverse events were mild and included erythema and mild swelling that resolved without intervention. Mild treatment area numbness was reported by 73% of subjects at the 4-week interim visit and fully resolved at the 12-week visit.

Conclusion: This study documents the first reported customized approach for assessment and treatment of arm fat using a small or medium cup applicator with varied applicator placement. By incorporating one or two treatment cycles per arm in a single session, the issue of variable fat distribution in people's arms can be addressed. This approach was shown to be a safe and effective way to reduce unwanted arm fat with high patient satisfaction. Lasers Surg. Med. 50:732–737, 2018.
© 2018 Wiley Periodicals, Inc.

Key words: cryolipolysis; arm fat; non-invasive body contouring; non-surgical fat reduction

INTRODUCTION

Non-invasive body contouring procedures have gained popularity as patients seek treatments without the attendant surgical risks and down time. Cryolipolysis is a popular non-invasive fat reduction procedure that utilizes controlled cooling to non-invasively target subcutaneous fat. Cryolipolysis is based upon the greater susceptibility of lipid-rich adipocytes to cold injury compared to surrounding water-rich cells [1–3]. Numerous clinical studies have demonstrated the safety, efficacy, and tolerability of cryolipolysis in multiple areas [4–21].

Initial cryolipolysis arm studies investigated treatment using a flat parallel plate applicator [22–23]. Subsequently, an investigational device exemption (IDE) study was carried out using a prototype cooled cup applicator with a single cryolipolysis cycle per arm that recently led to US Food and Drug Administration clearance of cryolipolysis treatment for the arms [24,25]. The IDE arm study delivered cryolipolysis with a prototype applicator created by inserting a custom-machined metal insert into a traditional parallel cooling plate applicator

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and have disclosed the following: Jason Rivers and Marcie Ulmer are clinical investigators for ZELTIQ and have been clinical investigators for Allergan. Jason Rivers has also been a consultant and member of advisory boards for Allergan. There are no other relevant commercial disclosures.

Contract grant sponsor: ZELTIQ; Contract grant sponsor: Allergan.

*Correspondence to: Jason K. Rivers, BSc, MD, FRCPC, FAAD, Pacific Derm, Suite 200-2425 Hemlock Street, Vancouver, BC V6H 4E1, Canada.
E-mail: jason@pacificderm.ca

Accepted 18 February 2018
Published online 22 March 2018 in Wiley Online Library (wileyonlinelibrary.com).
DOI 10.1002/lsm.22811

© 2018 Wiley Periodicals, Inc.

(CoolFit applicator) to create a contoured cooling surface [24]. The prototype applicator had a cooling surface that was 6.3 inches (16.0 cm) in length. The subsequent commercial versions of the cooled cup applicators used in this study were of medium (CoolAdvantage applicator) and small (CoolAdvantage Petite applicator) size with cooling surface lengths of 6.0 inches (15.2 cm) and 4.5 inches (11.4 cm), respectively. The applicators were coupled with a flat contour (CoolFit) to seal against the arm.

Previously, and owing to the availability of only one applicator for the arms, many patients have been excluded from treatment as their arms were not appropriate for therapy. Having multiple commercial applicators allows the clinician to customize the treatment approach for a broader range of patients. While some patients can be treated with a single cycle centered on the arm bulge, other patients have larger bulges that would be more adequately addressed with end-to-end or side-to-side overlapping treatments. The medium and small cup lengths allow tailored treatment for different arm shapes. Rather than the single cycle protocol used in the arm IDE study, this current study protocol utilized a more realistic approach in which a customized treatment plan was carried out to address the excess subcutaneous fat. Thus, our study represents the first to investigate the concurrent use of two commercially available versions of the cooled cup cryolipolysis applicator for arm treatments in a single treatment session.

MATERIALS AND METHODS

This was a single center, prospective, open label, non-randomized interventional cohort study. The protocol was approved by an independent review board (Quorum Review IRB, Seattle, WA). Eligible subjects were male or female, between 18 and 65 years of age, and with clearly visible arm fat. Exclusion criteria included a prior fat reduction procedure in or near the treatment area, known history of cryoglobulinemia, cold urticaria, cold agglutinin disease, paroxysmal cold hemoglobinuria, Raynaud's disease, bleeding disorders, or concurrent medications that could increase the risk of bruising, and active implanted devices such as a pacemaker, defibrillator, or drug delivery system. Subjects with a history of carpal tunnel syndrome, compartment syndrome, or deep vein thrombosis in the upper extremities were also excluded from the study. Ideal study candidates had minimal skin laxity in the treatment area.

For the duration of the study, subjects were instructed to avoid implementing major diet or exercise changes to maintain their weight within 5% of baseline measurement. Prior to treatment and 12 weeks after treatment, caliper and circumferential measurements, ultrasounds, and photographs were obtained. Patient surveys were also conducted at the final follow-up visit.

Each subject received simultaneous bilateral arm cryolipolysis treatments with up to two treatment cycles per arm conducted in a single session. Non-invasive fat reduction procedures were carried out with an FDA-cleared cryolipolysis device (CoolSculpting System, ZELTIQ Aesthetics, Pleasanton, CA). Each treatment cycle (-11°C for 35 minutes) was delivered by a commercially available cooled cup vacuum cryolipolysis applicator (CoolAdvantage applicator or CoolAdvantage Petite applicator with CoolFit contour).

The applicators were placed within custom-made fixtures to ensure standard positioning and patient comfort, as described in the prior IDE study with a prototype applicator [24]. A protective gel pad (CoolAdhesive gel pad) was applied to the skin, the arm was positioned over the vacuum applicator, and suction was initiated. The vacuum adhered the applicator to the treatment area and the subject was seated throughout the cryolipolysis procedure. After each treatment cycle, vacuum was stopped and the subject's arm was removed from the applicator. A manual massage of the treatment area was performed for 2 minutes. If appropriate and based on the investigator's assessment, a second cryolipolysis treatment was delivered to each arm, oriented side-by-side, or end-to-end with approximately 25% overlap relative to the first treatment cycle. Figure 1 shows an example of side-by-side and end-to-end applicator placements with overlap in the center of the treatment area.

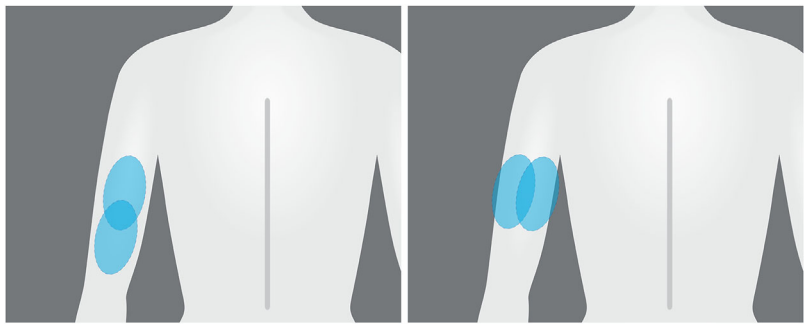

Fig. 1. Illustration of customized treatment based upon arm fat presentation. The length of the arm bulge was addressed by end-to-end applicator placement (left) and the width of the arm bulge was treated with side-by-side applicator placement (right) with approximately 25% overlap in the center.

Patient discomfort was monitored throughout the study procedures, immediately following device removal, prior to patient discharge, and at the 1, 4, 12-week follow-up visits. Pain was assessed on a scale from 0 to 10 periodically throughout the 35-minute cooling cycle.

Treatment efficacy was assessed by clinical photographs, caliper, and circumferential measurements, and ultrasound imaging. In the clinical photographs, subjects were positioned standing with their arms placed on a fixture. Their toes were positioned against a guideline that standardized the body position. Photos were taken at pre- and 12-week post-treatment visits using a standardized photography set-up (Nikon D810, Nikon 60 mm lens, 2 DynaLite strobes set to 125 W/s, black backdrop) to ensure consistency. Subsequently, baseline and final visit photos were reviewed by a blinded, independent panel of three physicians board-certified in either dermatology or plastic surgery. Independent photo review data was generated by randomizing pre- and post-treatment photograph pairs of each subject, then asking each reviewer to determine the pre-treatment image.

Ultrasound images were acquired at baseline and final visits. A transparent, flexible film template was applied to each arm to mark the ultrasound measurement areas and anatomical landmarks (e.g., moles and scars) to facilitate locating the same ultrasound sites in the follow-up visit. A 7.5 MHz high-resolution linear transducer was used to acquire ultrasound images of the treatment site (SonoSite TITAN, Bothell, WA). Care was taken to lightly stabilize the transducer without compressing the tissue. Ultrasounds were post-processed to measure anatomical features in the pre- and post-treatment images, and the subcutaneous fat layer reduction was calculated.

Caliper and circumference measurements were recorded pre-treatment and at 12 weeks post-treatment. Fat thickness caliper measurements were collected using a skinfold caliper (Harpenden skinfold caliper, Baty International, West Sussex, United Kingdom). Circumferential measurements were obtained using a digital tape measure (Health o meter, model HDTM012-69, Sunbeam Products, Boca Raton, FL).

Subject satisfaction data was collected by a written questionnaire at the 12-week final follow-up visits. This questionnaire was composed of 5-point Likert scale questions, as well as free-text responses. Safety was monitored by documentation of adverse events and clinical assessment of the treatment site. Subjects were assessed throughout the study for adverse events.

Statistical analysis was performed based on the nature of the data. Dichotomous (e.g., gender, blinded independent photo review) and ordinal (e.g., Fitzpatrick Skin Type) data were tabulated by category. The mean, standard deviation, maximum, and minimum were tabulated for continuous data (e.g., age, ultrasound fat layer reduction). The 0.05 significance level was calculated from a paired, two-tailed test.

RESULTS

Fifteen patients were enrolled and completed treatment. Of the 15 subjects, seven were treated with one cycle using the medium applicator, two were treated with one cycle using the small applicator, two were treated with two cycles using the medium applicator, and four were treated with two cycles using the small applicator.

All subjects were female and either Caucasian ($n = 12$), Asian ($n = 1$), or Other ($n = 2$) with Fitzpatrick Skin Type II ($n = 9$), Type III ($n = 4$), or Type V ($n = 2$). The subject ages ranged from 40 to 59 (mean 51.1 years). The average weight was 155.7 lbs (range 130.7–205.3 lbs), while Body Mass Index (BMI) ranged from 22.4 to 33.7 (mean BMI 26.8). All 15 subjects remained within the ±5% weight change limit and were included in efficacy analysis.

For the bilateral treatments on 15 subjects, 30 photograph pairs were available for analysis. From the independent photo review, three blinded, independent physicians reviewed the photographs in randomized pairs. The overall correct identification rate was 83% (75/90), with the three reviewers correctly identifying 28/30, 26/30, and 21/30 photo pairs each. Figures 2–4 show representative subjects at baseline and at 12 weeks after final treatment, and demonstrate visible reduction in subcutaneous arm fat.

Ultrasound measurement of fat layer thickness at the treatment areas was performed on both arms prior to treatment and at the 12-week post-treatment visit.

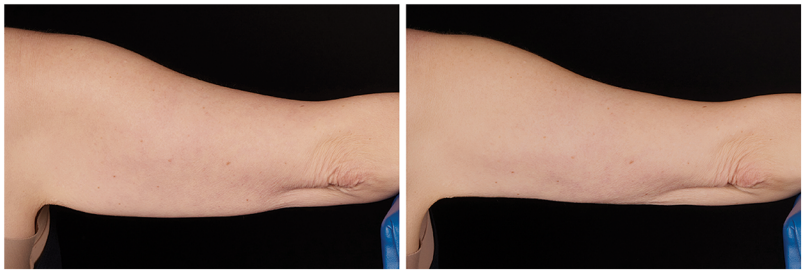

Fig. 2. Baseline (left) and 12-week post-treatment (right) photographs of a 58-year-old woman with an extended bulge of fat that would not have been adequately covered with a medium applicator. She was treated with two small cryolipolysis applicator cycles oriented end-to-end with approximately 25% overlap. Weight change −0.4 kg from baseline. Subject RIV-001.

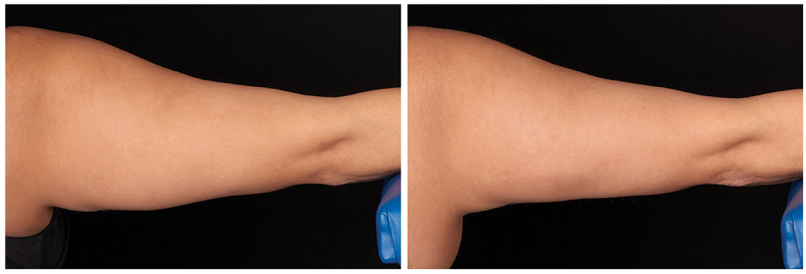

Fig. 3. Baseline (left) and 12-week post-treatment (right) photographs of a 40-year-old woman with a broad bulge of fat located distal to the axilla. She was treated with two small cryolipolysis applicator cycles oriented side-to-side with approximately 25% overlap. Weight change −1.7 kg from baseline. Subject RIV-006.

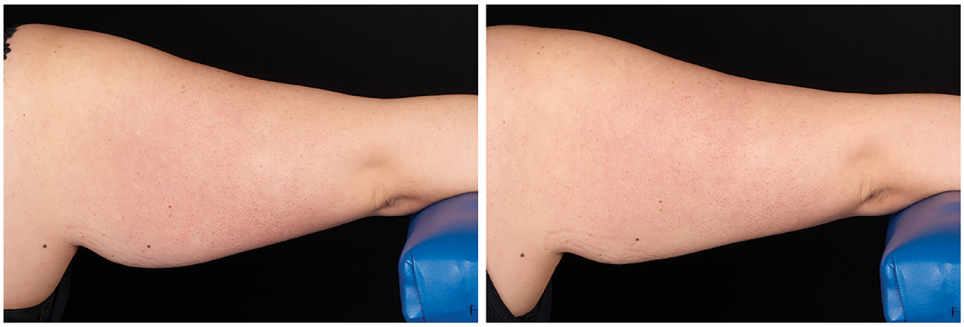

Fig. 4. Baseline (left) and 12-week post-treatment (right) photographs of a 41-year-old woman with a broad bulge of fat and long arm. She was treated with two medium cryolipolysis applicator cycles oriented side-to-side with approximately 25% overlap. Weight change −0.3 kg from baseline. Subject RIV-008.

Figure 5 shows representative ultrasound images captured at baseline and at 12 weeks after final treatment. The ultrasound analysis revealed a mean fat layer reduction of 2.5 mm (SD ± 2.4 mm, 95%CI 1.6–3.3), and a range from an increase of 2.4 mm to a reduction of 6.8 mm. The reduction in fat layer was statistically significant ($P < 0.05$).

Caliper measurement of fat layer thickness was performed on both arms prior to treatment and at the 12-week post-treatment visit. The treatment areas showed a statistically significant ($P < 0.005$) mean fat layer reduction of 1.3 mm (SD ± 1.42 mm, 95%CI 0.6–2.1), and a range from an increase of 0.3 mm to a reduction of 5.0 mm.

Circumference measurement was performed on both arms prior to treatment and at the 12-week post-treatment visit. The change in arm circumference ranged from an increase of 0.4 cm to a reduction of 1.6 cm, with a mean reduction in circumference of 0.7 cm (SD ± 0.28 cm, 95%CI 0.4–1.0) ($P < 0.01$).

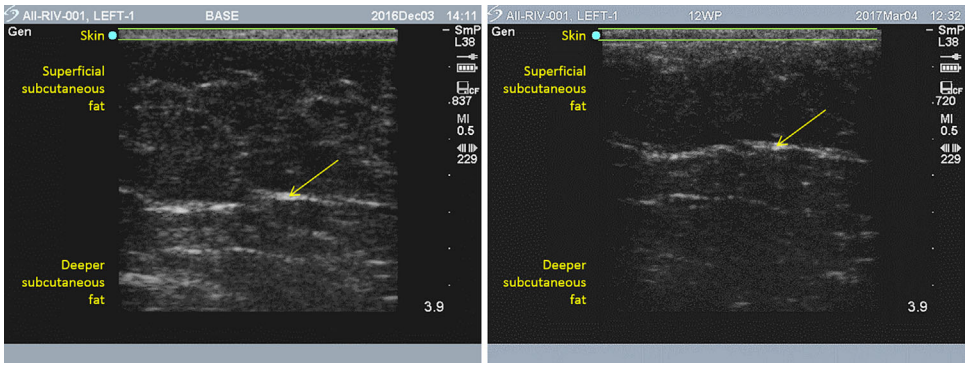

Fig. 5. Baseline (left) and 12-week post-treatment (right) ultrasound images. The skin layer is located at the top and the rest of image shows the subcutaneous fat layer. Arrows indicate change in position of the same collagen fiber within the fat layer pre- and post-treatment, demonstrating fat reduction. Subject RIV-001.

Patient survey data from the follow-up questionnaire were tabulated for all subjects. From the surveys, 87% of subjects were satisfied, 80% would recommend cryolipolysis to a friend, and 80% felt their appearance had improved after having the procedure.

Pain assessments were recorded during treatment, immediately after treatment, prior to patient discharge, and at the 1, 4, 12-week follow-up visits using a scale from 0 to 10. During treatment, the average pain score was 1.3 ± 0.9, immediately after device removal pain was 1.4 ± 2.0, and prior to discharge it was 1.0 ± 1.2. At the follow-up visits 1, 4, and 12 weeks post-treatment, all subjects reported a pain score of 0.

Clinical assessment of the treatment sites was performed immediately post-treatment and at the follow-up visits. At each time point, subjects were assessed for common adverse effects including erythema, edema, bruising, numbness, and tingling at the treatment site. Any other adverse event was also assessed and recorded. Immediately post-treatment, the most common adverse events within the treatment area were numbness, erythema, and bruising. By the 4-week follow-up visit, all these had resolved except for mild numbness in the treatment zone reported by 73% of subjects. At the 12-week final visit, all adverse events had resolved spontaneously. There were no reported device- and/or procedure-related complications, including paradoxical adipose hyperplasia.

DISCUSSION

This study is the first to evaluate safety and efficacy of the two recently released commercially-available small and medium cooled cup cryolipolysis applicators incorporating a customized treatment approach for the reduction of subcutaneous arm fat. While a previous IDE arm study established safety and efficacy of arm cryolipolysis, it utilized a protocol of a single cycle on each arm [24]. However, in the real world, patients present to their physician with variable degrees and localization of arm fat. This requires the development of a customized treatment plan which can now be addressed in a safe and time efficient manner using multiple applicators in a concurrent fashion, in one treatment session.

The efficacy of arm cryolipolysis in the current study confirms the findings from the earlier IDE arm study using the prototype cooled cup applicator [24]. The current study, using the commercial version of the cooled cup applicator, found an average 2.5 mm reduction of fat by ultrasound measurements, while blinded, independent photo reviewers correctly identified 83% of the baseline photos. This compares favorably with the earlier IDE arm study where there was an average of 3.2 mm fat layer reduction and 85% of baseline photographs were identified correctly [24]. Although the average 2.5 mm fat layer reduction from the current arm study is slightly lower than the previous arm study, the average fat layer reduction is consistent with other cryolipolysis studies (Table 1) [11,12,19,21].

TABLE 1. Fat Layer Reduction Measured by Ultrasound for the Current Arm Study is Consistent With Previously Published Cryolipolysis Studies

Treatment area (citation)	Fat layer reduction (mm)
Arms in current study	2.5
Arms [24]	3.2
Inner thighs [11]	2.8
Outer thighs [12]	2.6
Submental area [19]	2.0
Pseudogynecomastia [21]	1.6

In a similar fashion, 83% of current study photos were correctly identified by blinded, independent physician reviewers, which is consistent with the 79–94% correct identification from other published cryolipolysis studies [6,7,11,12,18,19,21,24].

We believe this is the first documented clinical study using simultaneous bilateral cryolipolysis treatments which may provide greater convenience to the patient and clinician due to reduced treatment time. This is also one of the few clinical studies which investigated overlapping cryolipolysis treatments. There have been flank and submental studies which employed two cryolipolysis cycles with 50% and 20% overlap, respectively [7,18]. The current study used approximately 25% overlap for arm treatments and found no increase in adverse events compared to the single applicator arm treatment study [24]. While some clinicians may be concerned that overlapping cycles may increase the risk of cold injury, the results from these studies suggest that multiple overlapping cryolipolysis treatments are safe and effective. While a single applicator cycle can be effective for many patients seeking arm fat reduction, having both the small and medium applicators and using overlapping treatment cycles adds versatility for treating all arm sizes. Our current arm cryolipolysis study with simultaneous bilateral treatments and multiple overlapping cryolipolysis cycles demonstrates efficacy and safety with no unanticipated short or long term adverse events, including ulnar nerve injuries or contour irregularities.

CONCLUSION

The safety and efficacy of using commercially-available small or medium cup cryolipolysis applicators, either alone, or sequentially in one treatment session was established. This customized approach allows for enhanced patient outcomes after a single visit and provides an option for those who would otherwise not be good candidates for cryolipolysis arm treatment.

ACKNOWLEDGMENTS

This clinical study was sponsored by ZELTIQ Aesthetics, manufacturer of the CoolSculpting System. ZELTIQ is an affiliate of Allergan, plc.

REFERENCES

1. Manstein D, Laubach H, Watanabe K, Farinelli W, Zurakowski D, Anderson RR. Selective cryolysis: A novel method of non-invasive fat removal. Lasers Surg Med 2008;40(9):595–604.
2. Zelickson B, Egbert BM, Preciado J, et al. Cryolipolysis for noninvasive fat cell destruction: Initial results from a pig model. Dermatol Surg 2009;35(10):1462–1470.
3. Avram MM, Harry RS. Cryolipolysis for subcutaneous fat layer reduction. Lasers Surg Med 2009;41(10):703–708.
4. Derrick CD, Shridharani SM, Broyles JM. The safety and efficacy of cryolipolysis: A systematic review of available literature. Aesthet Surg J 2015;35(7):830–836.
5. Ingargiola MJ, Motakef S, Chung MT, Vasconez HC, Sasaki GH. Cryolipolysis for fat reduction and body contouring: Safety and efficacy of current treatment paradigms. Plast Reconstr Surg 2015;135(6):1581–1590.
6. Kilmer SL. Prototype CoolCup cryolipolysis applicator with over 40% reduced treatment time demonstrates equivalent safety and efficacy with greater patient preference. Lasers Surg Med 2017;49(1):63–68.
7. Bernstein EF, Bloom JD, Basilavecchio LD, Plugis JM. Non-invasive fat reduction of the flanks using a new cryolipolysis applicator and overlapping, two-cycle treatments. Lasers Surg Med 2014;46(10):731–735.
8. Garibyan L, Sipprell WH, 3rd, Jalian HR, Sakamoto FH, Avram M, Anderson RR. Three-dimensional volumetric quantification of fat loss following cryolipolysis. Lasers Surg Med 2014;46(2):75–80.
9. Klein KB, Bachelor EP, Becker EV, Bowes LE. Multiple same day cryolipolysis treatments for the reduction of subcutaneous fat are safe and do not affect serum lipid levels or liver function tests. Lasers Surg Med 2017;49(7):640–644.
10. Boey GE, Wasilenchuk JL. Fat reduction in the inner thigh using a prototype cryolipolysis applicator. Dermatol Surg 2014;40(9):1004–1009.
11. Zelickson BD, Burns AJ, Kilmer SL. Cryolipolysis for safe and effective inner thigh fat reduction. Lasers Surg Med 2015;47(2):120–127.
12. Stevens WG, Bachelor EP. Cryolipolysis conformable-surface applicator for nonsurgical fat reduction in lateral thighs. Aesthet Surg J 2015;35(1):66–71.
13. Sasaki GH, Abelev N, Tevez-Ortiz A. Noninvasive selective cryolipolysis and reperfusion recovery for localized natural fat reduction and contouring. Aesthet Surg J 2014;34(3): 420–431.
14. Boey GE, Wasilenchuk JL. Enhanced clinical outcome with manual massage following cryolipolysis treatment: A 4-month study of safety and efficacy. Lasers Surg Med 2014;46(1):20–26.
15. Stevens WG, Pietrzak LK, Spring MA. Broad overview of a clinical and commercial experience with CoolSculpting. Aesthet Surg J 2013;33(6):835–846.
16. Dierickx CC, Mazer JM, Sand M, Koenig S, Arigon V. Safety, tolerance, and patient satisfaction with noninvasive cryolipolysis. Dermatol Surg 2013;39(8):1209–1216.
17. Suh DH, Park JH, Jung HK, Lee SJ, Kim HJ, Ryu HJ. Cryolipolysis for submental fat reduction in Asians. J Cosmet Laser Ther. 2018;20(1): 24–27.
18. Bernstein EF, Bloom JD. Safety and efficacy of bilateral submental cryolipolysis with quantified 3-dimensional imaging of fat reduction and skin tightening. JAMA Facial Plast Surg 2017;19(5): 350–357.
19. Kilmer SL, Burns AJ, Zelickson BD. Safety and efficacy of cryolipolysis for non-invasive reduction of submental fat. Lasers Surg Med 2016;48(1):3–13.
20. Harrington JL, Capizzi PJ. Cryolipolysis for nonsurgical reduction of fat in the lateral chest wall post-mastectomy. Aesthet Surg J 2017;37(6):715–722.
21. Munavalli GS, Panchaprateep R. Cryolipolysis for targeted fat reduction and improved appearance of the enlarged male breast. Dermatol Surg 2015;41(9):1043–1051.
22. Lee SJ, Jang HW, Kim H, Suh DH, Ryu HJ. Non-invasive cryolipolysis to reduce subcutaneous fat in the arms. J Cosmet Laser Ther. 2016;18(3):126–129.
23. Wanitphakdeedecha R, Sathaworawong A, Manuskiatti W. The efficacy of cryolipolysis treatment on arms and inner thighs. Lasers Med Sci. 2015;30(8):2165–2169.
24. Carruthers JD, Humphrey S, Rivers JK. Cryolipolysis for reduction of arm fat: Safety and efficacy of a prototype CoolCup applicator with flat contour. Dermatol Surg 2017;43(7):940–949.
25. FDA 510(k) K162050, arm clearance date November 21, 2016, www.accessdata.fda.gov/cdrh_docs/pdf16/K162050.pdf. Accessed September 15, 2017.